Subject: CREATE Act comments

The following comments are provided regarding the CREATE Act Interim Rules published in Volume 7, No. 7 of the Federal Register, Pages 1818-1824. The views presented are my own and should not be attributable to Foley & Lardner LLP or its clients.

I. New Rule 1.321(d) Should Be Consistent With Existing Rule 1.321(c)

New Rule 1.321(d)(4)(i) requires that terminal disclaimers include a provision waiving the right to separately <u>license</u> and <u>enforce</u> the rejected jointly owned application or patent and the disqualified patent owned by one of the parties to the joint research agreement.

However, preexisting Rule 1.321(c)(3) requires that terminal disclaimers include a provision waiving only the right to separately enforce the commonly owned patent application and patent.

There is no reason for Rules 1.321(c) and (d) to be inconsistent and for Rule 1.321(d) to place a larger burden on applicants submitting terminal disclaimers under the CREATE Act. I believe that the prohibition on separate licensing in Rule 1.321(d) would present a serious burden on the patent owners and would present serious obstacles to licensing of patents because agreement of two separate licensors regarding two separate patents would be needed to complete a license agreement. Furthermore, the prior patent may already be exclusively licensed and thus could not be licensed to the same licensee as the later patent, thus significantly lowering the value of the later patent.

I propose that Rule 1.321(d)(4)(i) be amended to exclude the waiver of the right to separately license and should only include the waiver of the right to separately enforce.

II. The Term "Not Patentably Distinct" In Rule 1.109 Is Vague

Rules 1.109(a) and (b) use the term "... not patentably distinct from ..." This term is unnecessarily vague because it is not specifically defined in the Rules and lends itself to unpredictable interpretation by the examiners.

I suggest that this term be replaced with "... unpatentable under 35 U.S.C. 102 and/or 103 over ..." to provide more clarity and guidance to the examiners.

III. Rule 1.109(b) Is Inconsistent With The CREATE Act

A. Rule 1.109(b) requires both the later "rejected" application and the prior "other" patent to be made within the scope of the joint research agreement. This is inconsistent with the language and purpose of the CREATE Act.

The purpose of the CREATE Act was to avoid the use of the prior patent not made under a joint research agreement and owned by one party from being used as prior art against a patent application made under the joint research agreement and owned or co-owned by one or more other parties. Thus, the whole point of the CREATE Act is that the prior patent is not made under the joint research agreement and is owned at least in part by a different party from the later application. If the prior patent was made under the same joint research agreement as the later application, then the patent and the application are likely jointly owned by the same parties and the 35 USC 103(c)(2) and (3) are not required to disqualify the patent as prior art.

I suggest that Rule 1.109(b) be amended to recite that only the "application or patent under reexamination" is made as a result of activities undertaken within the scope of the joint research agreement.

B. The USPTO should only invoke the double patenting rejection under Rule 1.109(b) when applicant expressly invokes the CREATE Act (i.e., 35 USC 103(c)(2) and (3)) to overcome a rejection under 35 USC 102(e),(f) or (g) / 103(a) because the USPTO is not equipped to find and interpret joint research agreements that were not specifically provided by applicants to the USPTO.

Under Rule 1.109(b) as currently written, future patent litigation defendants may try to use Rule 1.109(b) to attempt hold otherwise valid patents invalid or unenforceable. In other words, it is possible that defendants in future litigations may argue that even through the CREATE Act was not invoked during the prosecution of a first patent, that the first patent is:

(i) invalid for obviousness type double patenting over a non-commonly owned, earlier second patent because the owner of the first patent had an undisclosed joint research agreement with the owner of the second patent, and/or

(ii) unenforceable for inequitable conduct because the patent owner failed to disclose the existence of the joint research agreement to the USPTO.

Therefore, with both above issues in mind, I propose that the first sentence of Rule 1.109 should read as follows:

- "A double patenting rejection will be made in an application or patent under reexamination if the application or patent under reexamination claims an invention that is <u>unpatentable under 35 U.S.C. 102 and/or 103 over</u> an invention claimed in a non-commonly owned patent, when:
- (i) the invention claimed in the application or patent under reexamination was made as a result of activities undertaken within the scope of the joint research agreement in which the owner of the non-commonly owned patent is a party; and
- (ii) 35 USC 103(c)(2) and (3) were used in the application or patent under reexamination to overcome a rejection."

IV) Rule 1.104(c)(4)(i) Is Vague

Rule 1.104(c)(4)(i) appears to be almost a verbatim copy of 35 USC 103(c)(1) and (2). Therefore this Rule provides little additional clarification to the statute.

Specifically, the following parts of the Rule are either vague or inconsistent:

A. 35 USC 103(c) uses the term "person" to mean one or more people or an organization. Therefore, the addition of the term "organization" in Rule 1.104(c)(4) makes the scope of the term "person" in this Rule inconsistent with the scope of this term in the Statute. Furthermore, Rule 1.104(c)(4) uses the term "person" without the term "organization" in the first sentences of paragraphs (4) and (4)(i) and then uses the term "person or organization" later in the same sentences, which makes it confusing.

Thus, I propose that the term "organization" should be deleted from this Rule.

B. It is unclear who the "parties" are in Rule 1.104(c)(4)(i)(A). First it seems that "parties" should be tied into "person" in 1.104(c)(4). Second, the term "on

behalf of parties" makes it is unclear if the application has to be a jointly owned by all parties to the joint research agreement.

For example party A solely owns a patent. Party A then signs a joint research agreement with party B. A sole inventor from party B then files a patent application on an invention that this inventor made within the scope of the agreement. It is unclear if 35 USC 103(c) can be used in this application to overcome a rejection over the patent.

Therefore, Rule 1.104(c)(4)(i)(A) should be clarified to explain if the patent application has to be jointly owned and/or have joint inventors from all parties to the joint research agreement to take advantage of 35 USC 103(c).

Respectfully submitted by:

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